IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON ELECTION WAVE CASES	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF EDWARD STANFORD, M.D.

Defendants Ethicon, Inc. and Johnson & Johnson submit this response in opposition to Plaintiffs' motion to exclude certain general opinions of Edward Stanford, M.D (Doc. 7349).

INTRODUCTION

Notwithstanding Plaintiffs' futile attempts to minimize Dr. Stanford's qualifications, Dr. Stanford is well qualified to testify about the opinions set forth in his report. A board-certified Obstetrician/Gynecologist, Dr. Stanford has implanted over 2000 patients with transvaginal synthetic mesh for the surgical treatment of stress urinary incontinence since 1999. Pl's Mot., Ex. C, Expert Report at 1; Ex. A hereto, CV.

Dr. Stanford's decades of clinical work are supplemented by his direct involvement in research, publication and teaching. He has served as a professor in the University of Tennessee Department of Obstetrics and Gynecology, served as the Chief of Urogynecology, and has been certified as an expert in complex fistula surgery by the International Society of Fistula Surgeons. *Id.* Dr. Stanford has written multiple articles published in peer-reviewed publications, and he has served as an editor of the Journal of Minimally Invasive Gynecology, the Female Pelvic

Medicine and Reconstructive Surgery Journal, the Journal of Robotic Surgery, and the International Urogynecology Journal. *Id.*

Plaintiffs could have deposed Dr. Stanford to ascertain more details about the basis for his opinions, but they chose not to do so. As set forth below, Plaintiffs' challenges to Dr. Stanford's opinions lack merit.

ARGUMENT

I. The Court should allow Dr. Stanford to offer opinions about warnings.

Dr. Stanford has opined on the completeness and accuracy of the IFU warnings from a clinical perspective based on his knowledge of and clinical experience with the devices. *E.g.*, Pl's Mot. Ex. C, Expert Rpt. at 18-20. Plaintiffs do not appear to challenge Dr. Stanford's clinical expertise. Instead Plaintiffs argue that Dr. Stanford's opinions are "not based on any industry standards or regulations governing the adequacy of warnings." Pl's Mot. at 3.

Ethicon concedes that Dr. Stanford is not a regulatory expert and will not opine on warnings from that perspective. Consistent with the Court's prior rulings, however, Dr. Stanford, as a urogynecologist, "may testify about the specific risks of implanting mesh and whether those risks appeared on the relevant IFU." *In re: Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig*, 2016 WL 4493666, at *4 (S.D.W. Va. Aug. 25, 2016). Dr. Stanford's report details his extensive experience with the devices, including particular risks and complications he has experienced and researched, and he explained why each of the IFU disclosures was accurate based on both his experience and the information relevant to the product. Pl's Mot. Ex. C, Expert Rpt. at 18-20

Dr. Stanford will testify that the complications that Plaintiffs allege should have been in the IFUs: (a) are risks that a pelvic surgeon would already know, and therefore, need not be warned about; (b) are not genuine complications; or (c) are not attributable to the device.

As it relates to the latter two categories, Dr. Stanford's report shows that his opinions are based on his extensive clinical experience, *as well as* his thorough critique of scientific literature. *See, e.g., id.* at 6-7 & n. 35-36. *See also Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 734-35 (S.D.W. Va. 2014) (allowing Dr. Johnson to testify about evidence of absence because his opinions were also based on medical literature); *Carlson v. Boston Scientific Corp*, 2015 WL 1931311 at *12 (S.D.W. Va. Apr. 28, 2015).[1]

Dr. Stanford, as an experienced clinician, is well qualified to testify about risks that are obvious to surgeons. Experts may testify as to the knowledge common within a profession or community. *See Flannery v. Bauermeister*, 2008 WL 77723, at *2 (D.R.I. Jan. 4, 2008) (granting summary judgment in part based on testimony from the defendants' experts as to what "is known within the correctional medical community"); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (allowing expert testimony of "common knowledge"); *U.S. v. Articles of Device*, 426 F.Supp. 366 (W.D. Pa. 1977) (FDA offered affidavit in misbranding case).

The law imposes no duty to warn sophisticated users of products with respect to risks that the sophisticated users already know or should know. *See, e.g.*, Restatement (Third) of Torts:

[1] While this Court has observed that "[a]bsence of evidence is not evidence of absence," *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 583-84 (S.D.W. Va. 2014), the observation only holds true where a cursory inquiry of the evidence has been made. For instance, if a physician is relying merely on his own experience to opine that a particular risk does not exist, the methodology may be flawed. However, where, as here, a physician examines the evidence outside of his own experience, such as by critiquing the medical literature and studying the conclusions of medical organizations, then the physician's opinions have a reliable basis. If there is no reliable evidence of risk as determined by a detailed review of appropriate sources, there is no obligation to include the risk in the IFU warnings.

Product Liability §2 cmt. j (1998); Restatement (Second) of the Law of Torts §402A cmt. j; American Law of Product Liability 3d § 32:69 (2016); *Willis v. Raymark Indus., Inc.*, 905 F.2d 793, 797 (4th Cir. 1990). In fact, 21 C.F.R. § 801.109(c) states there is no duty to warn if "the article is a device for which the hazards, warnings and other information are commonly known to practitioners licensed by law to use the device."

This is an objective test not dependent on the knowledge of the individual surgeon, and Dr. Stanford is certainly competent to share his opinions about what risks should be obvious to surgeons who use the devices and how an average clinician would construe the IFUs. Indeed, Ethicon writes its IFUs for pelvic floor surgeons like Dr. Stanford. Under the learned intermediary doctrine, such surgeons are the ones who must be adequately warned. If Plaintiffs intend to argue at trial that Ethicon's IFUs failed to disclose certain risks, then it is only fair that Ethicon be allowed to defend itself by demonstrating that those risks were obvious to the users of the product (pelvic surgeons and urologists), and therefore, did not need to be included in the IFUs in accordance with the aforementioned law.

Plaintiffs' other criticisms of Dr. Stanford's warnings opinions rely upon isolated statements that are taken out of context. Dr. Stanford merely opines that surgeons do not rely on IFUs as their primary means to make a decision as to whether or not to use a medical device. Instead, they primarily rely on their own research and experience. Pl's Mot. Ex. C, Expert Rpt. at 18-19. There is also no basis for Plaintiffs to accuse Dr. Stanford of "cherry-picking" merely because his report does not reference one article that Plaintiffs claim—without any support whatsoever—to be "seminal." *See* Pl's Mot. at 5.

Plaintiffs were welcome to explore Dr. Stanford's opinions further in deposition, but they declined to do so. Plaintiffs' nit-picking is suited for cross-examination and does not serve as a basis for exclusion.

Finally, it is ironic that Plaintiffs claim that Dr. Stanford's warning opinions are "not based on any industry standards or regulations governing the adequacy of warnings" (Pl's Mot. at 3), when Plaintiffs' own clinician experts do not base their warning opinions on any industry standards or regulations. Were the Court to accept Plaintiffs' standard, it should exclude the warnings opinions of Plaintiffs' experts.

II. Dr. Stanford's clinical experience is a proper basis for his opinions and is reinforced by peer-reviewed literature and other scientific evidence.

Citing a prior opinion of this Court, Plaintiffs claim that "an expert cannot relate precise statistics" about their clinical experiences unless the expert can set forth a reliable foundation for those statistics. Pl's Mot. at 6. But Plaintiffs do not identify any "precise statistics" that Dr. Stanford cites in his report about his personal experiences.

Instead, Plaintiffs attack Dr. Stanford for being vague – the exact opposite of precise. Their only specific challenge is to an innocuous statement in his report that "In my hands, I cannot recall a bladder or urethral injury in several years." Pl's Mot. at 6 (citing Ex. C thereto at 9). Plaintiffs do not explain why Dr. Stanford was required to retain a registry for something that he does not recall. *See Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Doc. 265, p. 40 (S.D. W. Va. Nov. 20, 2014) ("If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions"); *Winebarger v. Boston Scientific Corp.*, 2015 U.S. Dist. LEXIS 53892, at *99 (S.D. W. Va. Apr. 24, 2015) (finding that expert's inability to provide "exact statistics" about the outcome of his patients did not render his personal experience opinions unreliable and that "such

detail is not required under *Daubert* to opine as to '*large-scale* safety and efficacy of the Uphold device"); *Trevino v. Boston Scientific Corp.*, 2016 WL 1718836, at *33 (S.D. W. Va. Apr. 28, 2016) (same).

III. Dr. Stanford's opinions regarding degradation and immune response are grounded in extensive clinical experience reinforced by scientific literature.

Dr. Stanford sets forth opinions about degradation from a clinic perspective, stating that, even if degradation occurs, it does not have any clinical significance. Pl's Mot., Ex. C, Expert Rpt. at 15-16. Plaintiffs make an unsupported, conclusory assertion that Dr. Stanford "[c]learly . . . is not a man who is an expert in this area," but did not bother to take his deposition to explore his expertise. Pl's Mot. at 7.

In this litigation, this Court has consistently rejected similar challenges by Plaintiffs and allowed pelvic surgeons with similar expertise as Dr. Stanford to provide such opinions on the basis that the opinions are reliably grounded on the expert's clinical experience and his review of scientific literature. *See, e.g., Huskey*, 29 F. Supp. 3d at 734-35; *Carlson*, 2015 WL 1931311 at *12; *In re: Ethicon, Inc.*, 2016 WL 4493666, at *4.[2]

Again, Plaintiffs' challenge to Dr. Stanford's qualifications to discuss degradation is inconsistent with their position that Plaintiffs' own pelvic surgeon experts may testify about degradation. If Dr. Stanford is not qualified to testify about this issue, neither are Plaintiffs' clinician experts.

[2] Finally, and in the alternative, even if Dr. Stanford were not competent to testify that TVT polypropylene mesh does not degrade, he is still well qualified to testify that there is no reliable evidence that the mesh degrades and to explain to the jury why the foundation for Plaintiffs' experts' opinions of degradation is unreliable. Opining that mesh does not degrade is altogether different than opining that there is no reliable evidence that mesh degrades or that there is no reliable evidence that any degradation has clinical significance.

CONCLUSION

For the reasons stated herein, the Court should deny Plaintiffs' motion to limit Dr. Stanford's testimony.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this date I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
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